



Syphilis

Syphilis Rapid Test Device (Whole Blood/Serum/Plasma)

For professional in vitro diagnostic use only.

INTENDED USE

Atlas Syphilis Rapid Test Device (Whole Blood / Serum / Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to *Treponema Pallidum (TP)* in whole blood, serum or plasma to aid in the diagnosis of Syphilis.

SUMMARY

Treponema Pallidum (TP) is the causative agent of the venereal disease Syphilis. *TP* is a spirochete bacterium with an outer envelope and a cytoplasmic membrane.¹ Relatively, little is known about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the number of cases of Syphilis infection has markedly increased since 1985.² Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users.³ One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.⁴

Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. The antibody response to the *TP* bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.⁵

Atlas Syphilis Rapid Test Device (Whole Blood / Serum / Plasma) utilizes a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on membrane to detect *TP* antibodies (IgG and IgM) qualitatively and selectively in whole blood, serum or plasma.

PRINCIPLE

Atlas Syphilis Rapid Test Device (Whole Blood / Serum / Plasma) is a qualitative membrane device based immunoassay for the detection of *TP* antibodies (IgG and IgM) in whole blood, serum or plasma. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the device. After a specimen is added to the specimen well of the device, it reacts with Syphilis antigen coated particles in the test. This

mixture migrates chromatographically along the length of the test strip and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgG and IgM in specimens. If the specimen contains *TP* antibodies, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain *TP* antibodies, a colored line will not appear in this region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains Syphilis antigen coated particles and Syphilis antigen coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The Syphilis Rapid Test Device (Whole Blood / Serum / Plasma) can be performed using whole blood, serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood should be

stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.

- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices with droppers
- Buffer (for whole blood only)
- Package insert

Materials Required But Not Provided

Specimen collection containers

Centrifuge (for plasma only)

Timer

DIRECTIONS FOR USE

Allow the test device, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the device on a clean and level surface.
For **Serum or Plasma** specimens: Hold the dropper vertically and **transfer 2 drops of serum or plasma** (approximately 75 µL) into the specimen well (S) of the test device, and start the timer. See illustration below.
For **Whole Blood** specimens: Hold the dropper vertically and **transfer 1 drop of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not read results after 30 minutes.

INTERPRETATION OF RESULTS

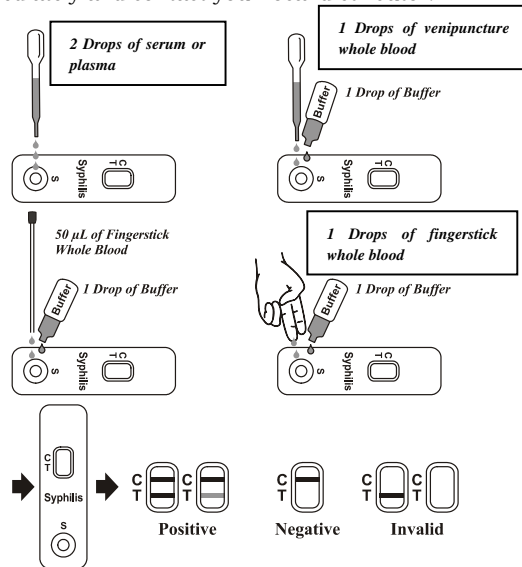
(Please refer to the illustration below)

POSITIVE: * **Two distinct colored lines appear.** One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *TP* antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. Atlas Syphilis Rapid Test Device (Whole Blood / Serum / Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *TP* antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *TP* antibodies can be determined by this qualitative test.

2. This test will only indicate the presence of *TP* antibodies in the specimen and should not be used as the sole criteria for the diagnosis of *TP* infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *TP* infection.

EXPECTED VALUES

Atlas Syphilis Rapid Test Device (Whole Blood / Serum / Plasma) has been compared with a leading commercial TPHA Syphilis test, demonstrating an overall accuracy greater than or equal to 99.7%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

Atlas Syphilis Rapid Test Device (Whole Blood / Serum / Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPHA Syphilis test using clinical specimens. The results show that the relative sensitivity of the Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) is 99.7%, and the relative specificity is 99.6%.

Syphilis Rapid Test Device vs. TPHA

Method		TPHA		Total Results
Syphilis Ultra Rapid Test Device	Result	Positive	Negativ	
	Positiv	384	2	386
	Negativ	1	493	494
Total Results		385	495	880

Relative Sensitivity: 99.7% (98.6%-100.0%)

Relative Specificity: 99.6% (98.5%-100.0%)

Relative Accuracy: 99.7% (99.0%-99.9%) 95% Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by testing 10 replicates of four specimens: a negative, a low positive, middle positive and a high positive. The negative, low positive, middle positive and high positive values were correctly identified 99% of the time.

Inter-Assay

Between-run precision has been determined by testing 10 replicates on the same four specimens: a negative, a low positive, middle positive and a high positive. Three different lots of Atlas Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) have been tested over a 3-month period using negative, low positive, middle positive and

high positive specimens. The specimens were correctly identified 99% of the time.

BIBLIOGRAPHY

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ATLAS MEDICAL

William James House, Cowley Rd,

Cambridge, CB4 4WX, UK
Tel: ++44 (0) 1223 858 910

Fax: ++44 (0) 1223 858 524

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